

AD \_\_\_\_\_

Award Number: DAMD17-00-1-0046

TITLE: Informed Consent for Prostate Screening with Prostate Specific Antigen in African Americans, Hispanics and Caucasians

PRINCIPAL INVESTIGATOR: Evelyn C. Chan, M.D., M.S.

CONTRACTING ORGANIZATION: University of Texas Health Sciences  
Center-Houston  
Houston, Texas 77225

REPORT DATE: February 2002

TYPE OF REPORT: Annual Summary

PREPARED FOR: U.S. Army Medical Research and Materiel Command  
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;  
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

20020909 038

# REPORT DOCUMENTATION PAGE

Form Approved  
OMB No. 074-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503

1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED	
	February 2002	Annual Summary (1 Feb 00 - 31 Jan 02)	
4. TITLE AND SUBTITLE Informed Consent for Prostate Screening with Prostate Specific Antigen in African Americans, Hispanics and Caucasians			5. FUNDING NUMBERS DAMD17-00-1-0046
6. AUTHOR(S) Evelyn C. Chan, M.D., M.S.			
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) University of Texas Health Sciences Center-Houston Houston, Texas 77225  E-Mail: <a href="mailto:Evelyn.C.Chan@uth.tmc.edu">Evelyn.C.Chan@uth.tmc.edu</a>		8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012		10. SPONSORING / MONITORING AGENCY REPORT NUMBER	
11. SUPPLEMENTARY NOTES			
12a. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited		12b. DISTRIBUTION CODE	
13. ABSTRACT (Maximum 200 Words) Because informed consent for prostate cancer screening with prostate specific antigen (PSA) is recommended, we determined how African Americans, Hispanics, and Caucasians want information about screening presented in culturally sensitive brochures specific for each group. We analyzed focus group discussions using content analysis and compared themes across groups. Twenty couples with men age 50 and older participated in four focus groups. There were content and graphic design differences in the way ethnic groups wanted information presented about the prostate, prostate cancer, risk, and screening. Caucasians likened the size of the prostate to a walnut; Hispanics, to a small lime. Hispanics emphasized how advanced prostate cancer can be symptomatic; Caucasians, how early prostate cancer can be asymptomatic. African Americans wanted risk information specific for them and the advantages and disadvantages of a PSA and DRE; Hispanics, did not. Caucasians and African Americans sought a more active role for men in informed decision making than Hispanics. Differences in the way African Americans, Hispanics, and Caucasians want information presented about prostate cancer screening suggest there may be cultural differences in the reasonable person standard of informed consent, in attitudes toward the physician-patient relationship, screening, and informed decision making.			
14. SUBJECT TERMS prostate cancer screening, prostate specific antigen, cultural sensitivity, informed consent		15. NUMBER OF PAGES 9	16. PRICE CODE
17. SECURITY CLASSIFICATION OF REPORT Unclassified	18. SECURITY CLASSIFICATION OF THIS PAGE Unclassified	19. SECURITY CLASSIFICATION OF ABSTRACT Unclassified	20. LIMITATION OF ABSTRACT Unlimited

NSN 7540-01-280-5500

Standard Form 298 (Rev. 2-89)  
Prescribed by ANSI Std. Z39-18  
298-102

## Table of Contents

<b>Cover.....</b>	<b>page 1</b>
<b>SF 298.....</b>	<b>page 2</b>
<b>Introduction.....</b>	<b>page 4</b>
<b>Body.....</b>	<b>pages 4-7</b>
<b>Key Research Accomplishments.....</b>	<b>page 7</b>
<b>Reportable Outcomes.....</b>	<b>page 7</b>
<b>Conclusions.....</b>	<b>page 7</b>
<b>References.....</b>	<b>page 7</b>
<b>Appendices.....</b>	<b>pages 8-9</b>

## **INTRODUCTION**

This research is a collaborative effort between The University of Texas Health Science Center at Houston Medical School, School of Public Health, and Texas Department of Health (TDH) to develop and pilot test culturally appropriate brochures about prostate cancer screening with prostate specific antigen (PSA) for African Americans, Hispanics, and Caucasians. Although PSA screening is widespread, knowledge of it is low. African American men have a higher incidence of prostate cancer, are more likely to be diagnosed at an advanced stage and have higher mortality rates than Caucasian men, but they remain largely ignorant about PSA screening. Hispanics are unlikely to know more about PSA screening than Caucasians since many emigrate from Latin American countries where preventive health care is not emphasized. Mass screening for prostate cancer with PSA is controversial because it is not clear whether it reduces the mortality from prostate cancer. Until clinical trials resolve this issue, informed consent for PSA screening is recommended. Studies suggest that culturally appropriate information about prostate cancer screening may promote knowledge, and thereby informed decision making about it, among minorities. In a preliminary study, the principal investigator (PI) asked experts in prostate cancer and couples what facts they believe men ought to know about PSA screening. Drawing upon their responses to arrive at a proposed standard of informed consent for PSA screening, the PI incorporated key facts about PSA screening into culturally appropriate brochures. She has convened focus groups of African American, Hispanic, and Caucasian couples to discuss the content and design of three brochures promoting knowledge about prostate cancer screening in each of the three ethnic groups. The PI will pilot test the brochures among men eligible for PSA screening to find out how well they comprehend them. She will work with the TDH to distribute brochures resulting from this proposal during Prostate Cancer Awareness Week. The brochures may also serve as culturally appropriate educational models for other State Departments of Health to follow.

## **BODY**

We first convened a focus group of 5 African American couples and a focus group of 5 Caucasian couples that each met twice. We also convened 2 Hispanic groups. This process is described below in accordance with the Statement of Work.

### **Phase 1: Project startup and recruitment of focus group participants**

The principal investigator (PI) hired a research assistant for recruiting focus groups and for assistance with data collection. Then the PI developed a preliminary patient brochure containing 17 key facts about the prostate specific antigen (PSA) test derived from the PI's preliminary study. The PI and research assistant then recruited focus group participants from a list of men age 50 or older who had been seen at The University of Texas Internal Medicine Clinic within the past year. We mailed a recruitment letter to African American (n=68) and Caucasian (n=121) men in June, 2000. We screened for eligible men through a brief telephone interview. Eligibility criteria included: men age 50 years of age or older, married with a living spouse, and no history of prostate cancer.

We also mailed an initial recruitment letter in English to Hispanic men (n=188) age 50 or older listed who attended the same clinic from June to August, 2000, a second recruitment letter in Spanish, and then followed up with a telephone call. We intensified our recruiting efforts with Hispanics since fewer responded to the former recruitment method alone. Caucasian men who participated ranged in age from 50 to 79 years old. The African American men who participated ranged in age from 56 to 73 years old. Hispanic men ranged in age from 51 to 73 years old. Their spouses were also invited to attend. The Hispanic participants were bilingual in Spanish and in English and were of Mexican descent. Phase I was completed with the meeting of the final focus group on April 10, 2001.

**Phase 2: To develop culturally appropriate brochures for African Americans and Caucasians and to review the preliminary study data with Hispanic couples**

We recruited focus groups of five Caucasian couples, five African American couples, and five Hispanic couples who each met twice, initially for four hours and then for two hours between August, 2000, and April, 2001. At the first focus group meeting, participants for each ethnic group were shown a 30-minute videotape entitled "*The PSA Decision: What YOU Should Know*" about prostate cancer and prostate cancer screening produced by the Prostate Outcomes Research Team in Dartmouth, VT. They were also shown a preliminary patient brochure containing 17 key facts about PSA screening that the PI had developed with the research assistant. Participants were asked to review the content of the brochure based on what they had learned from the videotape and based upon their own knowledge about prostate cancer screening. They were asked to provide suggestions on how to design a brochure targeted to men in their ethnic/racial group.

After transcribing the tapes from each focus group meeting, we found some differences in the approaches that each ethnic group would use. There were differences in content emphasis and in graphic design choices between the brochures that African Americans, Caucasians, and Hispanics would design for members of their racial/ethnic group. Because of the perceived discomfort and embarrassment associated with the digital rectal exam (DRE), African American men felt strongly that it was important to emphasize the advantages and disadvantages of screening with the DRE, as well as the PSA. Caucasian men did not discuss the DRE at all. African American men believed it was important to emphasize epidemiologic data specific to African American men, such as their higher risk of prostate cancer. They also preferred images and symbols rooted in African American culture (eg. Kente cloth). Hispanics and African Americans expressed concern about diet and exercise as risk factors for prostate cancer.

The PI and research assistant drew upon suggestions made at the first meeting of the focus groups to arrive at mock-up brochures for each focus group. These mock brochures were discussed at the second meeting of each group. Refinements in the design were made with attention to format, style, layout, and title of the brochure. The African American participants preferred graphic images reflecting family themes, for example, a picture of a man with his father. The Caucasian participants preferred graphic images reflecting lifestyle activities, such as a picture of a man barbequing or walking his

dog. All ethnic/racial groups wanted a diagram showing where the prostate is located relative to other anatomical structures and a picture of a man with his physician to highlight to readers the need to discuss prostate cancer screening with a physician. We contracted with an independent graphics design artist to complete brochure design for these three ethnic groups, based upon group suggestions made at the focus group meetings. The PI presented the mock-up brochures to members of the Texas Department of Health (TDH), State Prostate Cancer Advisory Committee in meeting held in January 2001 in Austin, Texas. The PI presented the brochures again after they were refined by a graphic design artist to members of the TDH, State Prostate Cancer Advisory Committee meeting held in November 2001 in Austin, Texas. The committee members were pleased with the design of each brochure, and offered minor changes and suggestions to the content information in each brochure. The brochures were also presented at the National Cancer Screening and Prevention Conference in September 2002 at the Centers for Disease Control and Prevention in Atlanta, Georgia.

In career development, the PI completed coursework in biostatistics at The University of Texas School of Public Health. Biometry II covered measurement problems, descriptive statistics, graphics, sampling distributions, hypothesis testing, comparisons of samples, non-parametric methods, regression and correlation theory, and computer applications. Biometry III covered one and two-way classification for attributes and measurements, analysis of discrete data, factorial experiments, and multiple regression analysis with computer applications. A course in clinical trial design offered through the University of Texas Medical School covered issues relating to the design of clinical trials, including randomization, blinding, sample size, baseline assessment and recruitment, data collection and quality control, participant adherence, health related quality of life, survival analysis, monitoring response variables, issues in data analysis, meta-analysis, and principles of applying the results of clinical trials to individual patients.

**Phase 3: To develop a culturally appropriate brochure for Hispanics and to pilot test all brochures developed on men eligible for prostate specific antigen screening to see how well they understand it and what impact it has on their knowledge of PSA**

We convened one group of 5 Hispanic couples. We asked them to review a video about prostate cancer and prostate cancer screening, as well as 17 key facts about it. They were asked to add any other key facts about prostate cancer screening that they believed men ought to know. They recommended adding eight additional facts. These included: the fact that the PSA test is painless; that screening for prostate cancer can be done annually; that there is no special diet or exercise program to prevent prostate cancer; that a man age 50 or older should discuss prostate cancer screening with his doctor; that a man may have no symptoms of early prostate cancer, but back pain and urinary problems if it is advanced; that in the digital rectal exam, the doctor uses a gloved finger to feel for abnormal lumps in the prostate; that the prostate is a gland about the size of a very small lime that surrounds the tube through which urine passes; and that the digital rectal exam can be embarrassing for some men. Hispanics preferred to include images of family and men of different ages in their brochure.

We recruited 5 more Hispanic couples for another focus group that met twice to review these facts and make recommendations about brochure design. We will pilot test all brochures developed to see how they impact upon patient knowledge after they are complete.

## **KEY RESEARCH ACCOMPLISHMENTS**

- Completion of career development coursework for principal investigator consistent with the career development requirements of this award.
- Completion of focus group discussions for Caucasians, African Americans, and Hispanics with identification of key areas of divergence in the way they would present information to their racial/ethnic group.
- Development of mock brochures for Caucasians, African Americans, and Hispanics that we are now refining with the assistance of a graphic design artist.
- Identification of content areas that members of each focus group wanted in brochures designed for members of their racial/ethnic group.
- Finalizing the brochure development with a graphic design artist.

## **REPORTABLE OUTCOMES**

- An abstract of the results from this work was accepted for presentation at the national meeting of the Society of General Internal Medicine in San Diego in May 2001, and at the Texas Cancer Council meeting in February 2002.
- A manuscript entitled, "Cultural Sensitivity and Informed Decision Making: How African Americans, Hispanics, and Caucasians Want Information About Prostate Cancer Presented" was submitted to the Journal of Family Practice on 24 January 2002. The abstract is included in the appendix.

## **CONCLUSIONS**

Differences in the way African Americans, Hispanics, and Caucasians want information presented about prostate cancer screening suggest there may be cultural differences in the reasonable person standard of informed consent, in attitudes toward the physician-patient relationship, screening, and informed decision making. Physicians promoting informed decision making about controversial screening tests should take cultural sensitivity into account when designing educational interventions and using them.

## **REFERENCES**

The preliminary work mentioned in this report was published as:

Chan ECY, Sulmasy DP. What should men know about prostate specific antigen screening before giving informed consent: Am J Med. 1998;105:266-274.

## **APPENDIX**

See the following page with an abstract from the manuscript submitted to the Journal of Family Practice. Results from this work were also presented at the annual meeting of the Society of General Internal Medicine in May 2001, and at the Texas Cancer Council meeting in February 2002.

## **Abstract**

**Objective:** Because informed consent for prostate cancer screening with prostate specific antigen (PSA) is recommended, we determined how African Americans, Hispanics, and Caucasians want information about screening with PSA and the digital rectal exam (DRE) presented in culturally sensitive brochures specific for each group.

**Study Design:** We analyzed focus group discussions using content analysis and compared themes across groups.

**Population:** Twenty couples with men age 50 and older participated in four focus groups.

**Outcome Measures:** Main outcome measures were participants' views on the content and graphic design of culturally sensitive brochures promoting informed decision making.

**Results:** There were content and graphic design differences in the way ethnic groups wanted information presented about the prostate, prostate cancer, risk, and screening. Caucasians likened the size of the prostate to a walnut; Hispanics, to a small lime. Hispanics emphasized how advanced prostate cancer can be symptomatic; Caucasians, how early prostate cancer can be asymptomatic. African Americans wanted risk information specific for them and the advantages and disadvantages of a PSA and DRE; Hispanics, did not. Caucasians and African Americans sought a more active role for men in informed decision making than Hispanics.

**Conclusions:** Differences in the way African Americans, Hispanics, and Caucasians want information presented about prostate cancer screening suggest there may be cultural differences in the reasonable person standard of informed consent, in attitudes toward the physician-patient relationship, screening, and informed decision making. Physicians promoting informed decision making about controversial screening tests should take cultural sensitivity into account when designing educational interventions and using them.

**Key Words:** prostate cancer screening, prostate specific antigen, cultural sensitivity, informed consent